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K092896
OCT 29 2010

REMPRESS Contrast Delivery System 510(k) Summary

Contact Name: Jim Knipfer
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Proprietary Name: REMPRESS
Common Name: Injector System
Classification Name: Injector and Syringe, Angiographic
Predicate Device(s): Angiomat Illumena Injector, K963071
Angiomat 6000 Injector, K860204

Intended Use:

The contrast delivery system REMPRESS is an intravascular injection system intended for the administration of contrast media or normal saline used in conjunction with angiographic imaging procedures.

Description:

The main components of the REMPRESS are the Console, Powerhead and Main Control Unit. The basic configurations of the REMPRESS are a pedestal or table mount configuration. With either configuration the three main components are most often contained in the angiographic suite and normally in close proximity to the patient. The parameters of the injection, such as volume, flow rate and pressure are programmed by the operator via the graphical user interface with touchscreen input. The Console is powered via 24 volts DC which is derived from a remote AC to DC converter (similar to that used with laptop computers) and communicates with Main Control Unit communications interface cable. After the injection protocol has been set, the Powerhead performs the injection by driving the lead screw ram. The ram pushes the push-rod of the syringe which expels fluid from the barrel of the syringe. The following paragraphs provide more details for each of these main components.

POWERHEAD: The Powerhead provides a means for accepting and identifying a given syringe and then applying a force to the plunger of the syringe via its screw driven ram which will eject the contrast or normal



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POWERHEAD: The Powerhead provides a means for accepting and identifying a given syringe and then applying a force to the plunger of the syringe via its screw driven ram which will eject the contrast or normal saline from the barrel of the syringe. The Powerhead is in constant communications with the Main Control Unit for determining injection protocol and to monitor all Powerhead functions and injection sequences. The Injection information is communicated to the user Console to provide immediate feedback of injection operation.

CONSOLE: The Console is the main user interface for the REMPRESS. It provides a color graphical user interface with an overlying touchscreen for easy injection monitoring and injection setup. At the completion of an injection the injection results are clearly displayed to the user. The Console provides a connection for a remote Handswitch that can be used to start or stop an injection. The Console resides normally in the angiographic suite and is typically located near the patient.

MAIN CONTROL UNIT: The Main Control Unit is the interface between the Console and the Powerhead. The Main Control Unit receives the user input data from the Console and converts to the necessary control information then relays to the Powerhead. The Main Control unit also provides the power necessary to operate the Powerhead. The Main Control Unit is located inside the angiographic suite and communicates with the Console via a communications link.

The system is designed to deliver a variety of injection protocols. The REMPRESS injection system is also provided with a variety of consumables products for connecting the syringes to the patient.

SUBSTANTIAL EQUIVALENCE

A comparison chart shown in Table 1 compares the technological characteristics of the REMPRESS contrast delivery system to the predicate devices the Liebel-Flarseim's Angiomat Illumena and Angiomat 6000. The REMPRESS is substantially equivalent to the predicate devices. The REMPRESS injector system safely and effectively injects contrast or saline solutions as desired by the user.



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Characteristic/ Feature	Angiomat 6000 (Predicate device)	Angiomat Illumena (Predicate Device)	REMPRESS (New Device)
Multi-phasic Contrast Injections	9 phases per protocol	4 phases per protocol	1 phase per protocol
Protocol Storage	99 protocols	99 protocols	20 protocols
X-ray/Scan Delay	0 – 255 secs.	0 – 300 secs.	0 – 99 secs
Inject Delay	0 – 255 secs.	0 – 300 secs.	0 – 99 secs
Inter-phase Delay	None	0 – 300 secs.	None
Inject Interval	None	0 – 300 secs.	None
Syringe System	260ml, 150ml, or 125ml	150ml or 125ml	150ml
Volume Remaining Display	Mechanical Scale on Powerhead	LED display on Powerhead	LED Display on Powerhead
Filling Rate	3 to 25ml/sec	3 to 25ml/sec	0.5 – 2.5ml/sec
Flow Rate	0.01 to 40ml/sec for 125/150ml syringe 0.01 to 59ml/sec for 260ml syringe	0.01 to 40ml/sec for 125/150ml syringe	0.1 to 25ml/sec with 150ml syringe
Pressure Limit	100 to 1200 PSI	75 to 1200 PSI	50 – 1200 PSI
Remote Start Switch	Yes	Yes	Yes
Safety Stop Mechanism	Electrical stop when injection parameters are out of specification	Electrical stop when injection parameters are out of specification	Electrical stop and mechanical backup stopper when injection parameters are out of specification
User Interface Features			
- Fill / Expel Control	Push button on head	Push button on head	Push button on head
- Air Detection	Operator visual inspection	Operator visual inspection	Operator visual inspection
- Programming Injection	Keypad	Touchscreen	Touchscreen
- Status Display	Powerhead lights	Powerhead lights	Powerhead lights
Materials	Plastics and metals	Plastics and metals	Plastics and metals
Anatomical Sites	Arterial and Venous injections	Arterial and Venous injections	Arterial and Venous injections
Intended Use Statement	The Angiomat 6000 is designed to inject radiopaque contrast medium into the vascular system for Angiography procedures as prescribed by qualified health care professionals.	The Angiomat Illumena is designed to inject radiopaque contrast medium into the vascular system for Angiography and CT procedures as prescribed by qualified health care professionals.	The contrast delivery system REMPRESS is an intravascular injection system intended for the administration of contrast media or flushing solutions used in conjunction with angiographic imaging procedures.
Target Population	Humans	Humans	Humans
Sterility	Consumables are provided sterile	Consumables are provided sterile	Consumables are provided sterile



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SUMMARY OF PERFORMANCE TESTING

Performance testing was completed in order to verify the REMPRESS contrast delivery system was capable of achieving the specification parameters for the system as outlined in the substantial equivalence chart. Verification of the system's ability to accurately achieve these values validates the substantial equivalence claims. Injection performance was tested to verify accuracy of delivered flow rate, volume, pressure and manual control speeds.

VOLUME

Fluid delivery of an injector is characterized by three primary parameters, flow rate, volume and pressure limit. The volume delivered is the most critical parameter in that it has the greatest effect on image quality. During testing, the volume delivered was accurately measured and compared to the volume programmed. Over the range of volumes programmed, the REMPRESS system successfully delivered the volumes within the allowable specifications.

FLOW RATE

The second most critical variable parameter in delivering fluid to a patient is the flow rate. During the test injections, the injection time and volume were recorded then the flow rate calculated. In the event of a pressure limit injection, the volume and time are known not to accurately represent the flow rate therefore the data was omitted from this specific calculation. In all non-pressure limited injections the flow rate measured within the allowable ranges of the specification. NOTE: Pressure limit injections automatically reduce the flow rate from the user set flow rate to maintain a constant pressure, as desired by the operator.

PRESSURE

During all injections, the injector monitors the pressure in order to determine if the injection should be pressure limited. An upper limit is set for each syringe type used in the injector in order to avoid failure of the syringe. During testing, the actual pressure was measured and compared to the displayed values and product specifications. All pressure readings were within the allowable specifications.

MANUAL CONTROL SPEEDS

The REMPRESS has two speeds for manually moving the rams. By depressing the forward or reverse keys on the Powerhead, the rams can be moved at varying speeds. By pressing the forward or reverse key in combination with the accelerator key, the rams can be moved at maximum speed. During testing, speeds were confirmed to be within the allowable specification range.



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CONCLUSION

The REMPRESS contrast delivery system provided its ability to perform within its specified parameters. As a result, its performance is deemed acceptable and substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Nemoto Kyorindo Co, Ltd.
c/o Mr. Jim Knipfer
Executive Director, Technical Center
2-12-4 Aoki, Kawaguchi
Saitama, JAPAN 332-0031

OCT 29 2010

Re: K092896
Trade/Device Name: REMPRESS
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector and Syringe
Regulatory Class: Class II (two)
Product Code: DXT
Dated: October 18, 2010
Received: October 25, 2010

Dear Mr. Knipfer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

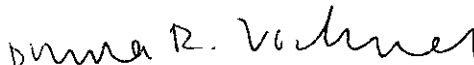
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

OCT 29 2010

Indications for Use

510(k) Number (if known): K092896

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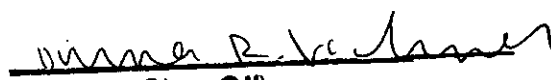
Prescription Use O
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Cardiovascular Devices

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